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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,446	05/08/2006	Teruo Nishida	868_007	4642

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BURR & BROWN
PO BOX 7068
SYRACUSE, NY 13261-7068

EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	**PAPER NUMBER**
1651	
MAIL DATE	**DELIVERY MODE**
12/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,446	NISHIDA ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This Office Action is in response to the Applicant's reply received 10/14/09. Claims 9-13 are pending. No Claims are withdrawn. Claims 1-8 and 14 are cancelled. Claim 9 has been amended. No Claims are new. Claims 9-13 are considered in this Office Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/09 has been entered.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant the following 35 U.S.C § 102 rejections are withdrawn:

- Claims 9-12 as being anticipated by Livant et al. (U.S. Patent # 6140068, 2000).

The Applicant's amendments requiring the extra components (ii) and (iii) necessitated the above withdrawal.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 9-13 over Livant et al. in further view of Alm et al. were considered but not found persuasive.

The Applicant argues that the limitation of "an ophthalmologically effective amount of the peptide…or a salt thereof" requires that the claimed composition "function as an ophthalmologic agent" and this feature is not taught in the cited prior art. However the direction by M.P.E.P. § 2112.01 provided states:

> A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

In the dependant claims the "ophthalmologically effeictive amount" of PHSRN is limited to a concentration of 0.00001% to about 1% or more specifically 2 µM to about 2000 µM. The art of Livant et al. meets this limitation. Furthermore there is nothing in Livant et al. or Alm et al. that would preclude one of ordinary skill of the art from administering the solution to the eye. Indeed Alm et al. even teach that compositions of fibronectin can be formulated into an eye drop to heal epithelial lesions (Alm, col 1, lines 13-15). Therefore the rejection of the remaining claims under Livant et al. in view of Alm et al. remains and is repeated below with some editing to meet the recent amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9- 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Livant et al. as applied to claims 9-12 above and in further view of Alm et al. (U.S. Patent # 5733870) with support of Answers.com.

These claims are to a composition comprising:

I. An ophthalmologically effective amount of peptide PHSRN or pharmaceutically acceptable salt;
II. A tonicity agent such as NaCl or KCl;
III. A buffer agent comprising sodium hydrogen phosphate or sodium dihydrogen phosphate;
IV. At least one member selected from the group consisting of an excipient, a lubricant, a builder, a disintegrator, a coating agent, a film-forming agent, a preservative, a base material, a stabilizer, and a pH adjuster.

The ophthalmologically effective amount of peptide is limited in claims 10 and 11 to a concentration of about 2 μM to about 2000 μM.

Livant et al. teach a composition comprising normal saline, which has a tonicity agent and excipient, with the peptide PHSRN (calculated MW = 609.64 g/mol) at a concentration of 660 μM (Example 11). Normal saline inherently contains the tonicity agent sodium chloride dissolved in water as the excipient.

While Livant et al. teach saline in their composition they do not teach the lubricants petrolatum or liquid paraffin nor the phosphate buffering agent. Regardless

this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Alm et al.

Alm et al. teach that ointments containing liquid paraffin or phosphate buffered saline combined with fibronectin is useful for wound healing such as epithelial lesions (Alm, Abstract, col 1, lines 30-35 and Example 1, 3 and 4). Alm et al. even references that fibronectin solutions are used in eye drops to treat epithelial lesions (Alm, col 1, lines 13-15). Phosphate buffered saline inherently contains sodium hydrogen phosphate as supported by Answers.com (definition-phosphate buffered saline) However Livant et al. teaches that both fibronectin and PHSRN induce fibroblast invasion which is attributed to accelerate wound healing (Livant, see Example 7, Fig. 4 and Example 12, Fig. 9 and 10). Also Livant et al. teach that PHSRN is a peptide sequence derived from fibronectin. Therefore since Livant et al. teach that both fibronectin and PHSRN are effective at wound healing it would be obvious that one of ordinary skill in the art would recognize that both are art-recognized compounds for the same purpose and it would be obvious to substitute one for the other (M.P.E.P. § 2144.06 II) and obtain predictable results in wound healing ((KSR Int'l Co. v. Teleflex, Inc. 550 U.S. 398 (2007)).

Therefore claims 9-13 are obvious in view of the above references.

No claims are currently allowed in this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims

(MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651